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| EXAMINER | |
|---|---|
| BUSTAMANTE, ERIK J | |

| ART UNIT | PAPER NUMBER |
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| 3766 | |

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/764,106 | LANGER, ALOIS A. | |
| | Examiner | Art Unit | |
| | Erik J. Bustamante | 3766 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/04, 2/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the lines, numbers, and letters are of poor line quality. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Therefore, the:

- "The emergency level detector" in claim 1
- The "emitting of radiation into the patient's skin and detecting the degree of radiation scattering" in claim 5
- The "analog to digital converter" in claim 11
- The "emergency level verification system" in claim 15
- The "stored patient data" in claim 16
- The method described in claims 17-29, applicant is advised that a flow diagram would be sufficient.

must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant is further advised that in the specification paragraphs [0012, 0017] would have to be amended to clearly reference the newly submitted drawings since the specification as submitted refers to the drawings as "FIGURE."

***Claim Objections***

3. Claim 17 is objected to because of the following informalities: "the notification device" lacks sufficient antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3,6-8, 17-18, and 20-22 are rejected under 35 U.S.C. 102(a) as being anticipated by MARTHUR (2002/0103508 A1).

Regarding claim 1, MARTHUR discloses a physiological parameter measuring device (114), an emergency level detector in communication with the physiological parameter measuring device (36, paragraph [0020]), a notification device in communication with emergency level detector (92,98).

Regarding claim 2, MARTHUR discloses a defibrillator being included in the defibrillation system (16,18,110).

Regarding claim 3, MARTHUR discloses that the physiological parameter-measuring device generates an electrocardiogram (paragraph 36).

With regards to claim 6, MARTHUR discloses a wireless communication device (28,26), the rest of the claim language does not recite a positive limitation and is interpreted as intended use.

With regards to claim 7, MARTHUR discloses a transmitter (46), and a receiver (72). MARTHUR also discloses that the receiver (72) is in functional communication with emergency level detector via channel (34), (paragraph 32).

With regard to claim 8, MARTHUR discloses the use of a radio telemetry channel (26, paragraph [0031]).

In the matter of claims 17 and 18, MARTHUR discloses measuring an ECG signal (228), providing the physiological parameter measurement to an emergency level detector (230), determining if the physiological parameter is at an emergency level (232), activating a notification device (236), receiving a notification (240), utilizing a defibrillator to attempt to return the physiological parameter to a non-emergency level (242).

In the matter of claims 20 and 21, MARTHUR discloses providing the measured physiological parameter to an emergency level detector (230), using a wireless communication device (paragraphs 42,33,34).

In the matter of claim 22, MARTHUR discloses sounding an audio alarm (paragraph 47).

6. Claims 1-3,12,13,16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by MORGAN (5,593,426).

Regarding claim 1, MORGAN discloses a physiological parameter measuring device (18), an emergency level detector (16) in communication with the physiological parameter measuring device (Col 3 lines 12-14), and a notification device (21,38).

Regarding claim 2, MORGAN discloses the inclusion of a defibrillator (Col 2 lines 29-43).

Regarding claim 3, MORGAN discloses that the physiological parameter measuring device generates an electrocardiogram (Col 2 lines 28-48; Col 3 lines 8-11).

Regarding claims 12 and 13, MORGAN discloses a communication device (14) to communicate information from the emergency level detector to a central receiving station (Col 4 lines 1-5, 13-16).

Regarding claim 16, MORGAN discloses that the system compromises stored patient data (Col 4 lines 64-67; Col 6 lines 14-21).

7. Claims 1-3,9-10,14,17-18,22,24,26, and 28 rejected under 35 U.S.C. 102(b) as being anticipated by UNGER (3,724,455).

Regarding claims 1 and 9, UNGER discloses a physiological parameter measuring device (Fig 1 "ELECTRODES"), an emergency level detector (30), and an alarm (40) in communication with the emergency level detector (Col 4 lines 12-25).

Regarding claim 2, UNGER discloses a defibrillation system comprising a defibrillator (Col 4 lines 52-55).

Regarding claim 3, UNGER discloses the generation of an electrocardiogram (Col 1 lines 37-42).

Regarding claim 10, UNGER discloses an amplifier (28).

Regarding claim 14, UNGER discloses a ventricular fibrillation detector (Col 4 lines 52-55).

Regarding claim 17, UNGER disclose measuring an ECG signal (Col 1 lines 37-42), providing the physiological parameter measurement to an emergency level detector (Col 3 lines 49-52) determining if the physiological parameter is at an emergency level (Col 3 lines 52-60), activating a notification device (Col 3 lines 61-67), receiving a notification (Col 4 lines 22-25), utilizing a defibrillator to attempt to return the physiological parameter to a non-emergency level (Col 4 lines 52-55).

Regarding claim 18, UNGER discloses the generation of an electrocardiogram (Col 1 lines 37-42).

Regarding claim 22, UNGER discloses sounding an audio alarm for notification (Col 4 lines 22-25).

Regarding claim 24, UNGER discloses amplifying physiological parameter signals (Col 3 lines 45-48).

Regarding claim 26, UNGER discloses providing a signal to a central receiving station if the physiological parameter is at emergency level (Col 3 lines 61-67).

Regarding claim 28, UNGER discloses the use of a ventricular fibrillation detector (Col 4 lines 52-55).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNGER as applied to claims 1 and 17 above in further view of JOO (6,440,082 B1).

Regarding claim 4 and 19, UNGER discloses the claimed invention essentially as described above. However, UNGER does not disclose measuring blood flow as the physiological parameter. JOO teaches determining the heart pulse before administering a defibrillation shock (Fig 4 78; Col 2 lines 34-54; Col 7 lines 23-37), which is interpreted to be a measurement of blood flow. JOO teaches that doing so provides a way "to assist a caregiver in determing whether defibrillation therapy is appropriate in an emergency situation (Col 2 lines 21-24)."

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the invention of UNGER with a means/step for measuring blood flow in light of the teachings of JOO for the purpose of assisting a caregiver in determing whether defibrillation is appropriate in an emergency situation.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over UNGER modified by JOO as applied to claim 4 above, and further in view of JOHNSON et al (3,511,227).

Regarding claim 5, UNGER as modified by JOO renders the claimed invention as obvious as described above with the exception of measuring blood flow via the measurement of radiation scattering. JOHNSON teaches the use of radiation scattering in the measurement of blood flow (Col 1 lines 64-72; Col 2 lines 1-21).

JOHNSON teaches that this "accommodates accurate measurement of the flow characteristics (Col 1 lines 59-60)" of blood in vivo.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of UNGER as modified by JOO with means for measuring blood flow via radiation scattering in light of the teachings of JOHNSON for the purpose of providing accurate measurement of the flow characteristics of blood in vivo.

11. Claims 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNGER as applied to claims 1 and 17 above, and further in view of BREWER et al (6,263,238) and NAPPHOLZ (5,113,869) cited only as supporting evidence.

Regarding claims 11 and 25, UNGER discloses the claimed invention essentially as described above. However, UNGER does not explicitly disclose using an analog to digital converter to convert signals from the physiological parameter measuring device. The examiner takes the position that it is well known in the art to use analog/digital converters in the art of recording physiological measurements and that it would have been obvious to one with ordinary skill in the art at the time the invention was made to have used an analog/digital converter. As supporting evidence, the examiner cites the disclosure of BREWER, which discloses using an analog/digital converter (102) to convert analog signals from the physiological parameter-measuring device to digital ones (Col 5 lines 12-17). The examiner also cites the disclosure of NAPPHOLZ, which also discloses using an analog to digital converter (140) to convert analog signals

from the physiological parameter-measuring device to digital ones (Col 19 lines 7-9).

12. Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over UNGER as applied to claims 1 and 17 above, and further in view of NAPPHOLZ (5,184,615).

Regarding claims 15 and 29, UNGER disclose the claimed invention essentially as described above. However, UNGER does not disclose including a method of verification that the emergency level of a measured physiological parameter. NAPPHOLZ teaches the confirmation of an arrhythmia (108,109, Col 22 lines 48-63). NAPPHOLZ teaches that this is to "provide improved confirmation of the presence of ventricular fibrillation prior to initiating shock therapy (Col 6 lines 8-10)."

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the invention of either UNGER with a verification means/step in light of the teachings of NAPPHOLZ in order to improve confirmation of ventricular fibrillation prior to initiating shock therapy.

13. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over UNGER as applied to claim 17 above, and further in view of DAVIS et al (5,544,661).

Regarding claim 23, UNGER discloses the claimed invention essentially as described above. However, UNGER does not disclose paging a caregiver. DAVIS teaches using a paging system (115) during an emergency cardiac event that a patient experiences to notify a caregiver (Col 3 lines 27-30). DAVIS

teaches that this allows the caregiver to "intercept the patient at the hospital (Col 3 lines 27-30)."

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of UNGER with a step of paging a caregiver in light of the teachings of DAVIS for the purpose allowing the caregiver to intercept the patient at the hospital.

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,321,618 to GESSMAN: An apparatus and method for remotely controlling a defibrillator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erik J. Bustamante whose telephone number is 571-272-8820. The examiner can normally be reached on Mon-Fri (7:30 - 11:30 AM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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